K080782
Pg 1 of 2

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: March 12, 2008

1. Submitter:

JAN 30 2009

Name:	Taewoong Medical Co., Ltd. 1-5 Gomak-ri, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Republic of Korea 415871
Contact:	J.H. Nam /Director Phone +82 31 996-0641

2. Device:

Proprietary Name:	Niti-S Esophageal Stent
Common Name:	Prosthesis, Esophageal
Classification Name:	Esophageal Prosthesis
Classification:	21 CFR 878.3610
Product Code:	ESW
Third Party Reviewed:	NO

3. Predicate Device:

Microvasive Ultraflex Esophageal Stent System
Boston Scientific Corporation
K940838

Niti-S Stent & Introducer, Model Esophageal,
Taewoong Medical Co., Ltd
K041648

Cook Esophageal Z Stent with DUA Anti-Reflux
Wilson-Cook Medical
K011591

4. Description:

The proposed Niti-S Esophageal Stent consists of an implantable metallic stent and a flexible introducer system. The stent is a rigid, flexible, and expandable tubular device

K080782

made of a Nitinol wire that is intended to be implanted to restore the structure and/or function of the esophagus. This device also includes the introducer. Upon deployment, the stent imparts an outward radial force on the luminal surface of the duct to establish patency.

5. Indications for use:

Niti-S Esophageal Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

6. Technological Characteristics:

The proposed Niti-S Esophageal Stent is a self-expanding Nickel Titanium alloy (Nitinol) stent mounted on an introducer. The stent is available in multiple sizes. The proposed stent's body diameter is 16, 18 or 20 mm with a 30, 50, 70, 90, or 120 mm length and each head's diameter is 24, 26 or 28 mm and 15 mm in length. Physician preference and individual patient condition and/or anatomy will determine the appropriate size.

Niti-S Esophageal Stent is substantially equivalent to Microvasive Ultraflex Esophageal Stent System, Boston scientific Corporation K940838, Cook Esophageal Z Stent with DUA Anti-Reflux, Wilson-Cook K011591 and Niti-S Stent & Introducer, Model Esophageal, Taewoong Medical Co., Ltd K041648. The devices have the same intended use and self-expanding stents constructed of Nitinol. The stents are mounted on an introducer system; however the designs are different. The predicate Microvasive Ultraflex Esophageal Stent System is constrained onto the introducer system with knitted loop by pulling string. The Niti-S Stent & Introducer, Model Esophageal and the proposed Niti-S Esophageal Stent utilized a co-axial tube and the stents are constrained onto the introducer system shaft by the outer sheath by pulling outer sheath.

7. Performance Data:

Laboratory testing regarding characteristics was performed on the Niti-S Esophageal Stent to verify its safety and performance. A biocompatibility assessment was performed on the patient contact materials of the Niti-S Esophageal Stent.

8. Conclusions:

Taewoong Medical Co., Ltd. concludes that the Niti-S Esophageal Stent is safe and effective. It is substantially equivalent to the predicate devices, Microvasive Ultraflex Esophageal Stent System, Cook Esophageal Z Stent with DUA Anti-Reflux and Niti-S Stent & Introducer, Model Esophageal.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Taewoong Medical Co., Ltd.
c/o Cathryn N. Cambria, RAC
Consultant
Arkin Consulting Group, LLC
5536 Trowbridge Drive
DUNWOODY GEORGIA 30338

JAN 30 2009

Re: K080782
Trade/Device Name: Taewoong Niti-S Esophageal Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: FGE
Dated: December 23, 2008
Received: December 30, 2008

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080782

510(k) Number K K080782

Device Name: Niti-S Esophageal Stent

Indication for use: Niti-S Esophageal Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

✓

Prescription Use_____ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080782